less than 100 nanometers, of the type comprising anethol-phospholipid phase in aqueous, alcoholic or non alcoholic phase.

29 (amended). Alcoholic or nonalcoholic beverage according to claim 20, wherein the microemulsion is obtained by high-pressure homogenization or by an appropriate mixer at high speed.

REMARKS

Claims 20-27 and 29-45 are pending.

Claim 20 as amended, hereby, is the same as claim 28 (now canceled). That is, claims 20 is amended, hereby, by incorporating the subject matter of claim 28, therein. Claim 29 is amended, commensurately. A marked-up version of the amended claims is attached, as Appendix, in compliance with PTO rules.

Reconsideration is requested with respect to the rejection under 35 USC 112, first paragraph.

By the instant amendment, all claims are limited to the beverage "in the form of a submicron emulsion or micro-emulsion," which is enabled under 35 U.S.C. §112, first paragraph, according to the statement of the rejection. Therefore, the rejection under said paragraph is overcome.

Claims were rejected under 35 U.S.C. paragraph §112, second paragraph, for allegedly being indefinite because the scope of each of the phrases "acceptable as an additive" and "visible solubility" was unknown.

Regarding the word "visible solubility", the present specification (page 5, lines 10 to 14) explains that such a solubility corresponds to an emulsion containing insoluble oil droplets that are

invisible to the naked human eye. In other words, it means that the emulsion appearing to be a clear solution is, in reality, a true emulsion of insoluble droplets in an aqueous mixture. The emulsifier makes it possible to disperse essential oil in very fine droplets to the point where the droplets are invisible.

The phrase "acceptable as an additive in human food" is changed to read --acceptable for human consumption--, supported in the specification at page 3, lines 6-31. Applicants maintain the original phrase is definite under §112, paragraph 2, but amend the claim to expedite prosecution.

The rejection of claims under 35 USC 103(a) based on US 4944956 (Brun), alone, is rendered moot by the instant Amendment. All claims are limited, hereby, to the subject matter of claim 28, which was not rejected under §103 based on Brun, alone.

Reconsideration is requested with respect to the rejection under 35 USC 103(a) of claim 28 (now, claim 20) and claim 29 based on Brun in view of US 4966779 (Kirk).

First, Applicants submit that the rewording of claim 20, hereby, limits and overcomes the reasons for rejection set forth in point 11 of the Office action. The claims, now, clearly recite that the size of particles is limited to a diameter less than 100 namometers.

Secondly, Applicants submit that the aforesaid particle-size limitation renders the subject matter of claim 28 (now, claim 20) and 29 patentable under §103(a), statements in the Office action to the contrary notwithstanding, for the following reasons.

Brun teaches that clear ethanolic compositions become cloudy when they are diluted, but the reference is silent as to whether the emulsion is micronized and on the size of particles in the

compositions. Kirk provides no teaching or suggestion to overcome the fatal deficiencies in Brun.

The cited Kirk reference discloses an emulsion with an average droplet size of about 0.5 microns to about 8 microns, preferably from 0.5 micron to about 2 microns (Kirk column 4, line 32). In Example 2 (Kirk column 6, lines 5 and 6), the average emulsion droplet diameter is described as approximately 2 microns. The smallest droplet diameter described in Kirk is, thus, 0.5 micron, i.e., 500 nanometers. Moreover, at the droplet diameters described in Kirk, the reference, itself, teaches that the emulsion is not clear but, rather, appears as a milky emulsion (Kirk column 6, line 13).

On the contrary, the instant claimed invention is directed to a submicron emulsion or micro-emulsion composed of nanosomes, whose average diameter is *less than 100 nanometers*, which is five-fold smaller than the smallest droplet (i.e., 500 nanometers) in the Kirk emulsion. Thus, as opposed to the Kirk emulsions, the presently claimed invention is a clear emulsion, i.e., an emulsion with particle diameters so small it appears clear as if it were a real solution.

The clarity of the beverage according to the presented claimed invention results from the fact that it is in the form of a submicron emulsion or micro-emulsion composed of nanosomes, whose average diameter is less than 100 nanometers. Thus, the size of particles is so small that the particles are imperceptible to the naked eye and a clear phase is observed, comparable to a true solution, but comprising an emulsion.

Moreover, the milky emulsions disclosed in Kirk are incorporated into a food product as additives, as for cereal fortification and other nutritional uses. On the other hand, the emulsions

according to the presently claimed invention are used for preparing non alcoholic beverages, which become cloudy when they are combined with water.

Attention is, further, directed to the method of preparing small nanosomes as found in the presently claimed invention. As illustrated by examples, the microemulsion may be prepared by only mechanical treatment, which purpose is to reduce the droplet size in the emulsion and, thus, to increase the clarity and the physical chemical stability of said emulsion (present specification, page 5, lines 32 to 37). Not only high pressure homogenization or high speed mixer treatments may be used, but also a simple Polytron treatment (page 11 – Example 5, line 16, and Example 6, line 26; page 12 – Example 7, lines 11 and 12, and example 9, lines 31 and 32).

Concerning their response filed on May 10, 2001, Applicants meant to stress that subjecting the emulsion disclosed in Kirk to high pressure treatment or high speed grinder mixing causes the average particle diameter to be less than 100 nm; however, it will never cause a clear solution because this emulsion is not thermodynamically stable. Applicants submit that the chemical composition of the emulsion mixture is what allows for the apparent clarity of the emulsion and, so, the chemical composition of the emulsion disclosed in Kirk will always give milky emulsions.

Kirk teaches a composition of a water-miscible emulsion using specific proportions of (a) a fat-soluble vitamin, (b) a liquid edible vegetable oil, (c) a modified lecithin, (d) a sucrose ester, (e) a sorbitan monooleate, (f) a sugar alcohol and (g) water. The emulsion has an average droplet size of from about 0.5 micron to about 8 microns, preferably about 0.5 micron to about 2 microns,

compounds (c), (d) and (e) being surfactants. On the contrary, the beverage according to the instant claimed invention comprises only one type of surfactant, i.e, one phospholipid.

The emulsion disclosed in Kirk is stable, i.e., it is an emulsion which does not separate into oil and water phases upon standing. Such an emulsion is not a clear solution, because the particles are perceptible to the naked eye, as explained above. Moreover, the Kirk emulsion is not intended to be diluted before consumption, no anethol is described as being present, and vitamins are completely different compounds with completely different uses.

For one skilled in the art and who wishes to provide clear beverages containing anethol, the solubility threshold of which is greater for a given volume of alcohol than that such as indicated on the curve attached to the single figure of the instant patent application, it would not have been obviousness to micronize the emulsion disclosed in Kirk in order to have smaller particles.

In regards to claim 38, the §103 rejection of said claim is directed to a cloudy beverage, which is obtained by diluting a clear beverage according to present claim 20. Indeed, the first object of the presently claimed invention is to provide a beverage that is clear before diluting (with water), said beverage being intended to be used diluted, and said dilution causing clouding. Examples of such a clear beverage, which becomes cloudy upon diluting, is Pastis and other aperitif beverages like Pastis. In this respect, attention is directed to the present specification, page 1, lines 5 to 9, and page 2, lines 24 to 27.

Citation to, and reliance on, *In re Levin*, 84 USPQ 232 (CCPA 1949), in the statement of rejection was noted by Applicants. Reliance on *Levin* is, however, misplaced. Under the rule set

forth in *Levin*, the presently claimed invention, broadly (i.e., as defined in claim 28 and, now, claim 20 as amended), is patentable. Moreover, the facts in *Levin*, which led to the holding of unpatentability in that case, are readily distinguishable from the facts in the present situation.

According to the decision in *Levin*:

> No single reference shows all of the ingredients and steps set forth in the appealed claims. However, more than one reference may be properly considered in determining the patentability of claims. Accordingly, no point can be successfully made here that in the combined references upon which the tribunals of the Patent Office relied there was no clear disclosure or suggestion of each and every ingredient of the product . . . defined by the appealed claims.

84 USPQ at 233 (*emphasis added*). Thus, the holding of unpatentibility in *Levin* is expressly limited to fact situations in which "no point can be successfully made . . . that in the combined references . . . relied [upon] there was no clear disclosure or suggestion of each and every ingredient of the product."

Contrary to the fact situation that existed in *Levin*, however, "each and every ingredient of the product" presently claimed is *not* found in "the combined references relied" upon to reject the claims. As opposed to the prior art relied on to reject the claims in Levin, neither Brun nor Kirk contains a "clear disclosure or suggestion" (84 USPQ at 233) of anethol-phospholipid droplets – i.e., "nanosomes having an average diameter less than 100 nanometers" – as contained in the presently claimed invention. Thus, the holding in *Levin* is not controlling under the facts presented in the present situation.

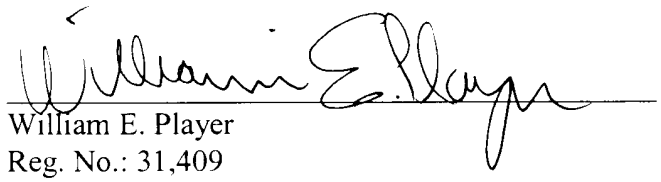
Levin, of course, did not find the claims unpatentable under 35 U.S.C. 103, since the decision antedated the changes in the patent laws occurring in 1952, which created Section 103. *Levin* is, however, consistent with post-1952 decisions holding that a finding of obviousness under Section 103 requires all claim limitations must be taught in the prior art in order to support a holding of obviousness, e.g., *In re Royka*, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970). When conducting an obviousness analysis, "all limitations of a claim must be considered in determining the claimed subject matter as is referred to in 35 U.S.C. 103 and it is error to ignore specific limitations distinguishing over the reference" relied on to reject the claims. *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App.1982).

In the present situation, however, neither of the references relied on to reject the claims, taken alone or in combination, describes aqueous emulsions containing anethol-phospholipid droplets of less than 100 nanometers in diameter, i.e., "a submicron emulsion or micro-emulsion composed on nanosomes having an average diameter less than 100 nanometers of the type comprising anethol-phospholipid phase" (claim 28 and claim 20, as amended). Therefore, the rejection of record against claim 28 under Section 103 was incorrect, and the same rejection cannot be maintained against claim 20 as amended, hereby.

Favorable action is requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By: 

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APPENDIX

Version with Markings to Show Changes Made

20 (amended). Alcoholic or nonalcoholic beverage containing anethol, comprising an effective amount of at least one phospholipid, acceptable [as an additive in human food, in order to improve the visible solubility of the anethol in said beverage] for human consumption, in the form of a submicron emulsion or micro-emulsion composed of nanosomes having an average diameter less than 100 nanometers, of the type comprising anethol-phospholipid phase in aqueous, alcoholic or non alcoholic phase.

29 (amended). Alcoholic or nonalcoholic beverage according to claim [28] 20, wherein the microemulsion is obtained by high-pressure homogenization or by an appropriate mixer at high speed.